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June 17, 2003

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EXTENSION: 833

PAGES (INCLUDING THIS PAGE): 3

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Dear Examiner Wilder,

This is in preparation for our telephone conference at 3 p.m. your time Wednesday.

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TELEPHONIC INTERVIEW OUTLINE

USSN 09/485,245

Hopkins "COMPOSITIONS COMPRISING RANDOM MIXTURES OF NUCLEOTIDES"

3:00 pm EDT Wednesday, June 18, 2003

Examiner Cynthia Wilder, Ph.D. 703-305-1680

1. OUTSTANDING REJECTIONS

a. Claims 1-5 stand rejected under 35 U.S.C. §103(a) Over Godiska, U.S. 5,759,804 in view of Shen EP 0 726 310.

b. Claim 6 stands rejected under 35 U.S.C. §103(a) over Godiska in view of Shen in view of Hoeltke.

2. APPLICANT'S INVENTION AND PATENTABILITY ARGUMENTS

a. The Invention and the State of the Prior Art:

i. The invention relates to an improvement in random priming methods where random sequence oligonucleotides are used to prime DNA synthesis on denatured template DNA at numerous sites along its length. The primer-template complex serves as a substrate for the "Klenow" fragment of DNA polymerase I and radioactive nucleotides are provided such that newly synthesized DNA is made radioactive.

ii. Various kits containing liquid solutions of oligonucleotides are known for practice of random priming methods. (Stratagene)

iii. While both short primers in solution such as those of Godiska (liquid 6-mers) were known there has been a trend toward using liquid solutions of longer primers in order to provide more rapid priming. (Megaprime and Ready-To-Go kits)

iv. Dried primer kits were known for use long primers. (Rediprime, EP 298,269 discloses 15-mers and 17-mers and Shen discloses 48-mers and 22-mers) Long dried primers were preferred to short dried primers because of the belief that such longer primers would provide more rapid priming than shorter primers.

v. The present invention relates to the discovery that there is a self-annealing problem with dried primers and that the solution to that problem is the use of shorter dried primers.

vi. The present invention is thus directed to dried mixtures of random primers and relates to the discovery that self-annealing occurs when random 9-mers are used in dried predispensed labeling kits. The problem is specific to 9-mers (and longer oligonucleotides) used in dried kits and does not represent a problem with shorter dried primers.

b. The Obviousness Rejections under 35 U.S.C. §103(a) Should be Withdrawn.

i. The Obviousness rejections under 35 U.S.C. §103(a) should be withdrawn because (1) the selection of 6-mers to 8-mers does constitutes a critical range (see the application examples) and (2) the art fails to suggest that short primers (6-8 mers) would be desirable in a dried primer system.

ii. Applicant's examples demonstrate a critical difference in self-priming activity and labeling intensity between 6-8 mers and 9-mers. (See Examples 2 and 4)

iii. There is nothing in Godiska that teaches (1) that the selection of 6-mers to 8-mers constitutes a critical range or (2) that short primers (6-mers to 8-mers) would be desirable in a dried system. Further, there is nothing in Godiska that teaches anything with respect to the issue of self-annealing.

iv. Shen relates to dried primers but discloses 48-mer and 22-mer primers (Example 1 and SEQ ID NOS 1 AND 2), and fails to make any suggestion that dried primers should be shortened or any reason why the primers of Godiska should be dried much less why dried 6-8 mers would be superior to dried 9-mers.